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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/879,139	06/19/1997	CARL R. MERRIL	P8026-7004	9154

7590 12/18/2002

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EXAMINER
WORTMAN, DONNA C

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/18/2002 22

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/879,139	MERRIL ET AL.	
	Examiner	Art Unit	
	Donna C. Wortman, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The request filed on October 25, 2002, for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/879139 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 31, 32, 34-37, 39 and 40 were last amended in Paper No. 8. Claims 31-40 remain pending and under examination.

Applicant is requested to update the status of parent application(s) to which reference is made in the first sentence of the specification.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reasons set forth on the Notice to Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures that was attached to the Office action remailed on April 25, 2002.

Applicant is given the same time period within which to comply with the sequence rules, 37 CFR 1.821 - 1.825, as is available to respond to this Office action. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Bracketing or underlining were previously commonly used to indicate amendments or changes in the claims and not normally intended to be printed in the published patent. In the amendment filed 12/12/97, Applicant has used underlining in

such a manner that it is unclear to the examiner whether the underlining is intended to appear in a patent. The underlining is unclear because in the amendment filed 8/10/98, underlining is apparently used to indicate inserted material. It is suggested that any underlined material that is intended to indicate genus and/or species of bacteria be deleted and replaced by italicized material in a clean copy of the amended claim or claims in accordance with the current Rule 121.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-40 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating an infectious disease caused by bacteria in non-human animals, does not reasonably provide enablement for treating an infectious disease caused by bacteria in a human patient. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The specification provides guidance for selecting bacteriophage that have a longer half-life by passaging through a non-human animal and then using the bacteriophage to treat an infectious disease caused by bacteria in animals of the same species as the animal in which the bacteriophage selection was done. There is no guidance particularly directed to selecting bacteriophage by passaging through humans, nor is there guidance for selecting bacteriophage by passaging through an animal or animals and then using animal-selected bacteriophage to treat humans. There is no indication

that a particular animal model is suitable for obtaining results related to bacteriophage treatment that could reasonably be extrapolated to treating disease in a human patient. One of skill in the art would require more than a mere assertion or a general indication that such procedures might be performed in order to successfully treat infectious disease in humans, given the state of the art at the time the invention was made with respect to using bacteriophage to treat human disease, the lack of knowledge of how the human immune system reacts to the presence of bacteriophage, and the unpredictability in the field. In this regard, Merril et al. (Proc. Natl. Acad. Sci. 93:3188-3192, 1996), listed on PTO 892, attached, is cited. Merril indicates that despite the development of a serial-passage method for selecting bacteriophage that circulate longer and are more efficacious in treating a bacterial infection in mice than the original bacteriophage, the ability to remain in circulation is only one of a number of difficulties in the general application of phage therapy, and that, even as of 1996, two years after the effective filing date of the instant application, the development of phage as a treatment for bacterial disease was incomplete (see, e.g., page 3192, last two paragraphs). In the absence of factual evidence that the disclosed methods for selecting bacteriophage and then using the selected bacteriophage for treatment are suitable for extrapolation to selection of bacteriophage for use in human treatment, the specification is not seen to enable one of skill in the art at the time the invention was made to select and use bacteriophage for human treatment as claimed, without undue experimentation and with a reasonable expectation for success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna C. Wortman, Ph.D. whose telephone number is 703-308-1032. The examiner can normally be reached on Monday-Thursday, 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 703-308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Donna C. Wortman, Ph.D.
Primary Examiner
Art Unit 1648

dcw
December 15, 2002